

## REMARKS

The Office action mailed 28 July 2003, has been received and its contents carefully noted. Claims 1-16 were pending and claims 8-14 were rejected. By this amendment, claims 9-14 have been canceled. No statutory new matter has been added. Reconsideration is respectfully requested.

### **Clarification of Previously Rejected Claims under 35 U.S.C. 112, second paragraph**

In the Office action of 14 February 2003, the Examiner rejected claim 8 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting steps. After the telephone interview with the Examiner on 7 May 2003, wherein the Examiner indicated that amended claim 8 by adding "whereby an increased level indicates an increase in the breast cancer and a decreased level indicates a decrease in the breast cancer" would be sufficient to overcome the rejection, Applicants amended claim 8 as agreed in the Response of 12 May 2003.

In the Office action of 28 July 2003, the Examiner stated that "Rejection of the claim under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps ... is withdrawn in view of the amendment". However, at other places in the same Office action, the Examiner indicated that claims 8-14 were rejected. Applicants believe that claim 8 as previously amended was meant to be expressly allowed by the Examiner. Applicants respectfully request that should claim 8 not be allowed, that the Examiner contact the undersigned to discuss and possibly enter an Examiner's Amendment rather than issuing an Advisory Action.

### **Rejection under 35 U.S.C. 103**

The Examiner rejected claims 9-14 under 35 U.S.C. 103 as being anticipated by Reilly *et al.* Specifically, the Examiner stated that although Reilly *et al.* does not teach or suggest combining instructions with the diagnostic reagent, it would have been obvious to do so.

Applicants respectfully disagree with the Examiner for the reasons provided in the prior response which is herein incorporated by reference. However, in order to advance prosecution Applicants have canceled claims 9-14. Therefore, the rejection under 35 U.S.C. 103 should properly be withdrawn.

### Allowed Subject Matter

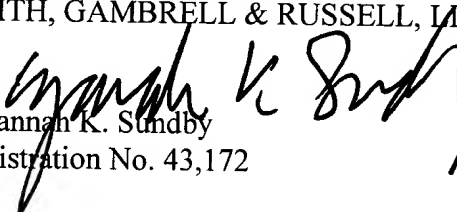
The Examiner indicated that the remaining claims, claims 1-8 and 15-16, are allowable. Therefore Applicants expect to receive a Notice of Allowance shortly. Should there be any remaining issues, Applicants respectfully request that the Examiner telephone the Attorney of Record below (please note the change of correspondence and new contact information).

### CONCLUSION

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, in the event that additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. §1.136(a), and any fees required therefor are hereby authorized to be charged to our Deposit Account No. **02-4300**, referencing Attorney Docket No. **034044.031 US** formerly P68884US0.

Respectfully submitted,  
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Date: 1 October 2003

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